

REMARKS

Favorable reconsideration of this application is respectfully requested. Claims 1, 6, and 10 are amended. Claims 3, 11-13, and 17-19 are also amended to be consistent with changes to claim 1. Claims 2 and 4-5 are cancelled without prejudice or disclaimer. Claim 20 is added. No new matter has been added. Claims 1, 3, and 6-20 are pending.

Claims 4-5 are objected to for informalities. The objection is rendered moot, as these claims have been cancelled. Claim 1, which now includes the subject matter of original claims 4-5, has been written to address the material classification issues raised with respect to claims 4-5.

Withdrawal of the objection is respectfully requested.

Claims 1, 6, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite. Applicants respectfully traverse this rejection.

Claim 1 recites a measuring step of an amount of a formed substance from the analyte by the redox reaction, and recites a determination step on the amount of the formed substance.

Claim 6 recites that the redox reaction is a color development reaction using an oxidase that involves reducing the oxidizing substance derived from the analyte and oxidizing a substrate that develops color by oxidation. That is, using the oxidase provides a reaction that includes reduction of the oxidizing substance and oxidation of the substrate, which results in color development.

Claim 10 recites that a fructosyl amino acid oxidase is caused to act on the analyte in the sample after eliminating the influence of the hemoglobin or the hemoglobin degradation product contained in the sample.

Applicants respectfully submit that the claims are definite in view of the foregoing. Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-11, 14, and 15 are provisionally rejected on the ground of non-statutory obviousness-type double patenting as being unpatentable over claims 7-14 of copending Application No. 10/521234. The rejection is rendered moot, as Applicants submit herewith a Terminal Disclaimer to overcome the rejection. Applicants, however, do not

concede the correctness of the rejection, and reserve the right to submit arguments with respect to any of the rejected claims at a later time.

Withdrawal of the rejection is respectfully requested.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Komori et al. (U.S. Patent Application Publication No. US 2002/0025546). The rejection is rendered moot, as claim 1 includes the subject matter of claim 2. Applicants do not concede the correctness of this rejection.

Withdrawal of the rejection is respectfully requested.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Oshiro et al. (1982). Applicants respectfully traverse this rejection.

Claim 1 recites, that prior to the redox reaction, adding at least one of a sulfur-containing compound or adding at least one of a nitrogen-containing compound. Particularly, claim 1 recites the adding at least one from the group consisting of the following compounds: dodecylbenzenesulfonic acid sodium salt, lithium lauryl sulfate, 4-aminoazobenzene-4'-sulfonic acid sodium salt, 4-amino-4'-nitrostilbene-2,2'-disulfonic acid disodium salt, and 4,4'-diazidostilbene-2,2'-disulfonic acid disodium salt, or 2,4-dinitrophenol, p-nitrophenol, 2,4-dinitroaniline, p-nitroaniline, 4-amino-4'-nitrostilbene-2,2'-disulfonic acid disodium salt, nitrobenzene, sodium nitrite, and potassium nitrite.

Oshiro et al. does not disclose the features of claim 1, and particularly the cited reference does not disclose the recited compounds as used in claim 1. Oshiro et al. discloses using sodium lauryl sulfate in its method of hemoglobin determination. However, sodium lauryl sulfate is not a compound specified in claim 1. For at least this reason, Oshiro et al. does not anticipate claim 1. Further, Oshiro et al. mentions sodium nitrite in previous methods of hemoglobin determination. However, the cited reference does not show or describe sodium nitrite as used in the claimed invention, namely for measuring an analyte by adding it prior to a redox reaction, so as to eliminate an influence of the hemoglobin or a hemoglobin degradation product contained in a sample. Moreover, Oshiro et al. teaches against using sodium nitrite in hemoglobin determination methods, because it is unsuitable for automatic analysis due to its lability. Therefore, Oshiro et al. does not disclose or suggest the claimed invention. Applicants respectfully submit that claims 1-5 are distinguishable over Oshiro et al.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

Claims 1-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Komori et al. (above) in view of Oshiro et al. (above) and ATSDR Course: SS3054 (2001). Applicants respectfully traverse this rejection.

Claim 1 has been discussed. Claim 1 can provide advantages such that the influence of hemoglobin or its degradation product can be prevented without affecting the measurement system. (See for example page 3, lines 12-18 and Examples of Applicants' disclosure). As a result, more accurate determinations can be conducted that are useful for various clinical medicine testing. (*Id.*)

The cited references do not render the claimed invention obvious. Komori et al. does not disclose or suggest any of the compounds recited by claim 1. In fact, Komori et al. provides for adding a nitro compound and particularly 2-(4-iodophenyl)-3-(2,4-dinitrophenyl)-5-(2,4-disulfophenyl)-2H-tetrazolium salt. This compound is not one of the nitrogen-containing compounds of claim 1. In fact, none of the nitro compounds disclosed by Komori et al. qualify as the compounds required by claim 1. Oshiro et al. does not disclose or suggest the features of claim 1. As noted, Oshiro et al. discloses using sodium lauryl sulfate in its method of hemoglobin determination. This compound is not one of the sulfur-containing compounds of claim 1. Therefore, the claimed invention is distinguished over Komori et al. and Oshiro et al.

Furthermore, Komori et al. and Oshiro et al. do not describe the advantageous effects that may be enjoyed by the features of claim 1. Therefore, there is no suggestion or motivation in Komori et al. and Oshiro et al. to arrive at claim 1.

ATSDR Course: SS3054 (2001) (hereafter "ATSDR") does not remedy the deficiencies of Komori et al. and Oshiro et al. Therefore, Applicants respectfully submit that claim 1 and dependent claims therefrom are patentable over Komori et al., Oshiro et al., and ATSDR, taken together or separately.

Favorable reconsideration and withdrawal of the rejection are respectfully requested.

With respect to new claim 20, Applicants respectfully submit that the prior art of record does not disclose or suggest a method for measuring a glycated protein in a sample

containing hemoglobin or a hemoglobin degradation product by using a redox reaction, as required by claim 20. Applicants respectfully request favorable consideration of this claim.

With the above amendments and remarks, Applicants believe that the pending claims are in a condition for allowance. Favorable consideration in the form of a Notice of Allowance is respectfully requested. If any further questions arise, the Examiner is invited to contact Applicants' representative at the number listed below.



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Respectfully submitted,

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